

**United States Court of Appeals
for the Federal Circuit**

**NOVARTIS AG AND
NOVARTIS VACCINES AND DIAGNOSTICS, INC.,**
Plaintiffs-Appellants,

AND

DANA-FARBER CANCER INSTITUTE,
Plaintiff,

v.

**MICHELLE K. LEE, Deputy Director,
United States Patent and Trademark Office,**
Defendant-Cross Appellant.

2013-1160, -1179

Appeals from the United States District Court for the District of Columbia in Nos. 10-CV-1138, 11-CV-0659, and 11-CV-0821, Judge Ellen S. Huvelle.

Decided: January 15, 2014

SCOTT S. CHRISTIE, McCarter & English, LLP, of Newark, New Jersey, argued for plaintiffs-appellants. With him on the brief was MARK H. ANANIA.

DANA KAERSVANG, Attorney, Appellate Staff, Civil Division, United States Department of Justice, of Washington, DC, argued for defendant-cross appellant. With her on the brief were STUART F. DELERY, Acting Assistant Attorney General, and RONALD C. MACHEN, JR., United States Attorney. Of counsel on the brief were BERNARD J. KNIGHT, JR., General Counsel, NATHAN K. KELLEY, Deputy Solicitor, and BRIAN T. RACILLA and JOSEPH G. PICCOLO, Associate Solicitors, United States Patent and Trademark Office, of Alexandria, Virginia.

DAVID P. FRAZIER and JENNIFER A. JOHNSON, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, of Washington, DC, for amicus curiae AbbVie Biotherapeutics Inc.

Before NEWMAN, DYK, and TARANTO, *Circuit Judges*.

TARANTO, *Circuit Judge*.

Novartis AG, Novartis Vaccines and Diagnostics, Inc., and Novartis Corporation (collectively, Novartis) filed suits that challenged the determinations by the Patent and Trademark Office of how much time to add, under 35 U.S.C. § 154(b), to the otherwise-applicable term of various Novartis patents. Of the eighteen patents before us, the district court dismissed Novartis's claims regarding fifteen as untimely asserted. For the other three, the court rejected the PTO's construction of the statutory provision that governs patent term adjustment here.

We affirm the district court's ruling on timeliness as to the claims at issue, agreeing with its interpretation of § 154(b)(3) and (b)(4). As to the standards for patent term adjustment, however, we conclude that the PTO was partly correct and partly incorrect in its interpretation of § 154(b)(1)(B). The result is that, for three patents,

Novartis is entitled to most, but not all, of the patent term adjustment it seeks.

BACKGROUND

In 1994, Congress changed the method of measuring the effective term of a patent. Before the change, a patent's term generally ran from the date that the patent issued until the end of a period measured from that date—typically seventeen years, subject to certain extensions (*e.g.*, those provided by the 1984 Hatch-Waxman Act, 35 U.S.C. § 156). Under the 1994 law, the term still begins on the issuance date, but it generally ends twenty years after the relevant application for that patent was filed. Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994) (revising 35 U.S.C. § 154). As a result, delays in processing the application at the PTO now reduce a patent's term.

In 1999, Congress provided for extensions of patent terms to compensate for certain application-processing delays caused by the PTO. *See* Pub. L. No. 106-113, § 1000(a)(9), 113 Stat. 1501, 1536. Specifically, 35 U.S.C. § 154(b)(1) makes three “[p]atent term guarantees”—“(A) Guarantee of prompt patent and trademark office responses,” “(B) Guarantee of no more than 3-year application pendency,” and “(C) Guarantee of adjustments for delays due to derivation proceedings, secrecy orders, and appeals.” The statute provides that “the term of the patent shall be extended 1 day for each day” that the PTO does not meet certain response deadlines, § 154(b)(1)(A), for each day after the PTO fails to issue the patent within three years, subject to exclusions, § 154(b)(1)(B), and for each day of delay due to an interference, secrecy order, or successful applicant appeal, § 154(b)(1)(C).

This appeal involves § 154(b)(1)(B), which builds on a goal of application pendency of three years, reflecting the replacement of a term of seventeen years from issuance by a term starting at issuance but ending twenty years after

application. *See* S. Rep. No. 105-42, at 42. The provision states:

(B) Guarantee of no more than 3-year application pendency.— Subject to the limitations under paragraph (2), if the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application under section 111(a) in the United States or, in the case of an international application, the date of commencement of the national stage under section 371 in the international application, not including—

(i) any time consumed by continued examination of the application requested by the applicant under section 132(b);

(ii) any time consumed by a proceeding under section 135(a), any time consumed by the imposition of an order under section 181, or any time consumed by appellate review by the Patent Trial and Appeal Board or by a Federal court; or

(iii) any delay in the processing of the application by the United States Patent and Trademark Office requested by the applicant except as permitted by paragraph (3)(C),

the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.

35 U.S.C. § 154(b)(1)(B) (2011).

The PTO regulations call for implementing this provision in two steps. First, “the term of an original patent shall be adjusted if the issuance of the patent was delayed

due to the failure of the Office to issue a patent within three years after the date on which the application was filed . . . , but not including (1) [a]ny time consumed by continued examination of the application under 35 U.S.C. 132(b)” 37 C.F.R. § 1.702(b)(1). Second, if an applicant is entitled to an extension, “[t]he period of adjustment . . . is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed . . . and ending on the date a patent was issued, but not including . . . (1) [t]he number of days, if any, in the period beginning on the date on which a request for continued examination of the application under 35 U.S.C. § 132(b) was filed and ending on the date the patent was issued” 37 C.F.R. § 1.703(b)(1).

In 35 U.S.C. § 154(b)(3) & § 154(b)(4), Congress provided administrative and judicial remedies for applicants who are dissatisfied with the PTO Director’s determination of a patent term adjustment. First, under § 154(b)(3)(B)(ii), an applicant must have “one opportunity to request reconsideration of any patent term adjustment determination made by the Director.” Second, under § 154(b)(4)(A), in the version applicable here (before recent revisions), “[a]n applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action against the Director filed in the United States District Court for the District of Columbia within 180 days after the grant of the patent.” *Id.* The PTO has interpreted the 180-day statute of limitations to apply to all patent term adjustment determinations, including those made under § 154(b)(1)(B)(i).

Between June 2009 and May 2011, Novartis filed four lawsuits in the District Court for the District of Columbia claiming that, for twenty-three of its patents, the Director had improperly determined the amount of patent term adjustment. *See, e.g.*, Second Amended Complaint, ¶ 2, *Novartis AG v. Kappos*, No. 10-cv-1138 (D.D.C. April 9,

2012), ECF 28. (In two of the cases, the Dana-Farber Cancer Institute was a co-plaintiff, but Dana-Farber has not appeared on appeal.) On February 16, 2012, the district court consolidated the cases.

Novartis claimed that the Director's determinations of the patent term adjustment rested on two mistaken interpretations of § 154(b)(1)(B)(i) as it applies to an applicant's request for continued examination under 35 U.S.C. § 132(b)—a process, authorized by Congress in 1999, through which an applicant may try to persuade an examiner to allow an application after an otherwise-final rejection. First, as previously mentioned, the Director treated time spent in any continuing examination, no matter when initiated by the applicant, as not counting toward the statute's allotment to the PTO of three years before adjustment time begins to accrue. Second, the Director treated as not counting toward the three years both the time from initiation of continued examination to allowance and, in addition, the time from allowance to issuance—even though the latter period is undisputedly counted toward the three years in a case not involving a continued examination. Novartis argued that both interpretations were contrary to § 154(b)(1)(B).

Novartis made two additional claims of relevance here. It claimed that it was entitled to have its patent term adjustments recalculated to conform to this court's decision in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), which held that the Director had taken an incorrect view of how § 154(b)(2) applies when there is "overlap" between "periods of delay" addressed by the statute. It is undisputed that Novartis would have received longer patent terms under the *Wyeth* standard. Novartis also claimed that denial of the statutorily authorized term adjustments constituted a taking of its property in violation of the Fifth Amendment.

The parties filed cross-motions for summary judgment, and on November 15, 2012, the district court dismissed Novartis's claims with respect to nineteen patents as untimely and granted Novartis relief on its remaining claims. *Novartis AG v. Kappos*, 904 F. Supp. 2d 58, 69 (D.D.C. 2012). For the claims dismissed as untimely, the court held that the applicable limitations rule was the 180-day rule of § 154(b)(4) and that nineteen of Novartis's claims—those filed more than 180 days after the PTO denied reconsideration of its adjustment determination—were filed too late under that rule. *Id.* at 65. The court thus rejected Novartis's contention that the 180-day limitations period did not apply to its challenges to final patent term adjustment determinations. Novartis appeals that ruling with respect to fifteen patents.

Of the four claims that the district court found timely, one sought a recalculation of a patent term adjustment to conform to *Wyeth*; the district court agreed, and neither party appeals that ruling. *Id.* at 74. Novartis's three other timely claims challenged the Director's interpretation of § 154(b)(1)(B). The district court ruled "that the PTO's interpretation of § 154(b)(1)(B) is contrary to law." *Id.* at 73. The Director cross-appeals that ruling. The district court did not reach the merits of Novartis's Fifth Amendment contention, which could not alter the untimeliness conclusion as to eighteen claims or add relief on the other claims. *Id.* at 74-75.

Both Novartis and the Director filed timely notices of appeal from the district court's final judgment. This court has jurisdiction under 28 U.S.C. § 1295(a)(4)(C).

DISCUSSION

The dispositive issues presented involve the meaning of two provisions of 35 U.S.C. § 154(b). Neither party identifies a material, disputed issue of fact. The correct interpretation of section 154 is an issue of law, which this court decides de novo. *See Wyeth*, 591 F.3d at 1369.

A

1

For fifteen patents, Novartis appeals the district court's dismissal of its claims as untimely under the pre-2013 version of 35 U.S.C. § 154(b)(3) & § 154(4)(A) that applies here. Those provisions state:

(3) Procedures for patent term adjustment determination. –

(A) The Director shall prescribe regulations establishing procedures for the application for and determination of patent term adjustments under this subsection.

(B) Under the procedures established under subparagraph (A), the Director shall--

(i) make a determination of the period of any patent term adjustment under this subsection, and *shall transmit a notice of that determination with the written notice of allowance* of the application under section 151; and

(ii) provide the applicant one opportunity to request reconsideration of any patent term adjustment determination made by the Director.

...

(4) Appeal of patent term adjustment determination.—

(A) An applicant dissatisfied with a determination made by the Director under paragraph (3) shall have remedy by a civil action *against the Director filed in the*

United States District Court for the District of Columbia within 180 days after the grant of the patent. Chapter 7 of title 5 shall apply to such action. Any final judgment resulting in a change to the period of adjustment of the patent term shall be served on the Director, and the Director shall thereafter alter the term of the patent to reflect such change.

35 U.S.C. § 154(b)(3) & (b)(4) (2011) (emphases added).

It is undisputed in this court that the 180-day clock does not run while the PTO considers a timely request for reconsideration under regulations promulgated pursuant to § (b)(3)(B)(ii)'s guarantee of "one opportunity to request reconsideration of any patent term adjustment determination made by the Director." It is also undisputed that, for the fifteen patents, Novartis did not file suit within 180 days of denial of reconsideration.

Novartis contends, however, that the 180-day period is inapplicable. Subparagraph (b)(4)(A) by its terms applies only to "a determination made by the Director under paragraph (3)" of subsection (b). Novartis asserts that a determination of the final patent term adjustment, announced upon issuance of the patent, is not made under "paragraph (3)," which, it says, addresses only the provisional adjustment announced upon allowance of claims (when the PTO process is not complete, so that the final adjustment cannot yet be calculated). Therefore, Novartis argues that the 180-day period is not applicable to its challenges to the final patent term adjustment determinations because, it says, the Director did not make those determinations under paragraph (b)(3). Novartis's contention thus turns on its interpretation of paragraph (b)(3). That interpretation is, ultimately, unreasonable.

The applicable version of paragraph (b)(3)—the whole of which subparagraph (b)(4)(A) refers to—addresses all

patent term adjustment determinations, not just some. Subparagraph (b)(3)(A) broadly declares that “[t]he Director shall prescribe regulations establishing procedures for the application for and determination of patent term adjustments under [(b)].” That breadth of application is reinforced by the breadth of at least clause (b)(3)(B)(ii) and subparagraph (b)(3)(D), both of which plainly cover the final adjustment announced at issuance, not just a provisional adjustment announced at allowance.

Novartis seeks to overcome the evident breadth of paragraph (b)(3) based on the language of clause (b)(3)(B)(i). That provision, in the version applicable here, states: “Under the procedures established under subparagraph (A), the Director shall—(i) make a determination of the period of any patent term adjustment under this subsection, and shall transmit a notice of that determination *with the written notice of allowance* of the application under section 151.” *Id.* § 154(b)(3) (emphasis added). Novartis infers from that language that all adjustment determinations covered by paragraph (b)(3) must be ones capable of being transmitted at the time of allowance, thus limiting paragraph (b)(3)—and therefore paragraph (b)(4)—to provisional determinations, excluding final determinations.

Although the statutory phrasing provides a starting point for Novartis’s argument, the inference Novartis draws is not a reasonable one given the rest of paragraph (b)(3). The only reasonable construction is that the (b)(3)(B)(i) command regarding transmittal with a notice of allowance is itself implicitly limited to determinations that can be transmitted at that time. Adopting that focused implicit limitation best fulfills the judicial obligation “to make sense rather than nonsense out of” the statute as a whole. *West Virginia Univ. Hosps., Inc. v. Casey*, 499 U.S. 83, 101 (1991) (noting obligation to do so for relevant “corpus juris”). This reading is far preferable to Novartis’s alternative, which would use one provision

to contradict the broad language of several other provisions and produce the senseless result that the detailed judicial-review provision of paragraph (b)(4)—with its 180-day rule and its confinement of venue to one district court—would apply to review only of provisional, but not final, adjustment determinations. In the end, the statutory language on which Novartis relies is a flaw in drafting that cannot reasonably support the construction Novartis advances.¹

2

Having rejected Novartis’s construction of paragraph (b)(4), we readily affirm the district court’s holding that Novartis’s claims as to fifteen patents were untimely asserted. Neither of Novartis’s two remaining arguments on timeliness has merit.

First, Novartis has not demonstrated that the 180-day rule of paragraph (b)(4) should be equitably tolled on the ground that Novartis could properly wait to challenge the PTO’s adjustment determinations until some other patentee undertook and completed the task of establishing the legal standard this court adopted in *Wyeth*. That is an insufficient ground for equitable tolling, which applies only if the litigant proves “(1) that he has been pursuing his rights diligently, and (2) that some extraordinary circumstance stood in his way’ and prevented timely filing.” *Holland v. Florida*, 560 U.S. 631, ___, 130 S.Ct. 2549, 2562 (2010). At a minimum, nothing stood in the

¹ Congress recognized the flaw and altered the language in the Technical Corrections to the Leahy-Smith America Invents Act, Pub. L. No. 112-274, § 1, 126 Stat. 2456 (2013). Clause (b)(3)(B)(i) now requires transmittal of an adjustment determination “no later than the date of issuance of the patent.” 35 U.S.C. § 154(b)(3)(B)(i) (2013).

way of Novartis's timely pressing the very claim Wyeth pressed. This court has held that a litigant cannot secure equitable tolling based on the argument "not that it lacked *sufficient facts* on which it could sue, but rather it did not know the *legal theory* on which its refund claim might succeed." *Venture Coal Sales Co. v. United States*, 370 F.3d 1102, 1107 (Fed. Cir. 2004); see *Commc'ns Vending Corp. of Arizona Inc. v. FCC*, 365 F.3d 1064, 1075 (D.C. Cir. 2004). A fortiori equitable tolling is unavailable where, as here, there is no reason even to doubt that the litigant knew the legal theory, but just waited until another person secured a favorable ruling on the theory in another case.

Second, there is no merit to Novartis's suggestion that its property was taken, in violation of the Fifth Amendment, when the paragraph (b)(4) timeliness rule, as construed and applied, eliminated its ability to secure the extra time on its patents that was authorized by the statute if timely sought.² It is sufficient for us to say that the Fifth Amendment does not "compensate the owner for the consequences of his own neglect" in preserving its rights. *United States v. Locke*, 471 U.S. 84, 107 (1985). For the patents as to which it did not timely file suit under § 154(b)(4), it was only Novartis's failure to comply with reasonable filing deadlines that prevented it from securing any patent term adjustment authorized by *Wyeth*. Novartis thus cannot challenge the application of the timing rule as an uncompensated taking.

² Novartis does not and cannot suggest that, for purposes of the Takings Clause, it has a property right in a patent term beyond what the statute entitled it to obtain. Its argument is that application of the timeliness rule took part of the patent term authorized by the statute.

B

Novartis timely challenged the Director's term adjustment for three patents at issue in this court—U.S. Patent Nos. 7,807,155, 7,968,518, and 7,973,031. The challenge concerns 35 U.S.C. § 154(b)(1)(B)(i) as it applies to continued examinations requested by Novartis. Novartis challenges two PTO interpretations of that provision. We agree with the PTO on one but not the other.

Novartis argues that, once three calendar years from the application-filing date have come and gone, time spent in the PTO after that date must be added to the patent term even if it is time spent on a continued examination requested after that date. In contrast, the PTO argues that “any time consumed by continued examination,” *id.* § 154(b)(1)(B)(i), no matter when initiated, does not count toward depleting the allotment of three years the PTO has before any adjustment time begins to accrue. In the PTO's view, no adjustment time is available for any time in continued examination, even if the continued examination was initiated more than three calendar years after the application's filing. On this point, we agree with the PTO.

The PTO's view is the approach that best accords with the language of the statutory provision. The provision indicates that the “3 years” (the goal for issuance) does “not includ[e]” time identified in three enumerated categories. In isolation, that language might be read, as two district courts have read it, to mean that the processes identified in the exclusions have no effect on the three-year time period unless they interrupt that period, *i.e.*, unless they were initiated before it ends. But that view runs counter to the textual fact that there is no time-of-initiation restriction on the processes identified in the exclusions, including continued examinations. *See id.* § 154(b)(1)(B)(i), (ii), (iii).

The better reading of the language is that the patent term adjustment time should be calculated by determining the length of the time between application and patent issuance, then subtracting any continued examination time (and other time identified in (i), (ii), and (iii) of (b)(1)(B)) and determining the extent to which the result exceeds three years. Such a reading ensures that applicants recover for any “delay[s] due to the failure of the [PTO],” without allowing the applicant to recover for “any time consumed by continued examination,” as the statute requires. *Id.* § 154(b)(1)(B)(i). Novartis has not given any persuasive reason that this reading of the statute is incorrect.

This construction is supported by the statutory purpose and other aspects of the statutory structure. The evident policy behind the three enumerated exclusions is that certain delays are not attributable to the PTO—delays not “due to the failure of” the PTO to move the process along, § 154(b)(1)(B)—and so should not count against the three years before adjustments begin. That focus on PTO responsibility or its absence does not distinguish continued examinations according to when they were initiated. Moreover, Novartis’s view, were it adopted for continued examinations, would seem to cover the parallel exclusion for “any time consumed by appellate review” in clause (b)(1)(B)(ii). The resulting extensions even for unsuccessful appeals, if initiated more than three years after the application’s filing, is in strong apparent tension with clause (b)(1)(C)(iii), which provides for extensions only for appeals that succeed. These considerations bolster our conclusion that the correct interpretation of the statute is the PTO’s view that time spent in a continued examination does not deplete the PTO’s allotment of three years for application processing before a resulting patent has its term extended, no matter when the continued examination begins.

While we thus disagree with Novartis on its first § 154(b)(1)(B) issue, we agree with Novartis on its second § 154(b)(1)(B) issue. Novartis argues that the “time consumed by continued examination” should be limited to the time before allowance, as long as no later examination actually occurs. In contrast, the PTO contends that any time up until the patent issues, even after allowance, should be excluded from the adjustment awarded to the patentee. We reject the PTO’s view that the time after allowance, until issuance, is “time consumed by continued examination” and so is excluded from adjustments given to the patentee. Such time from allowance to issuance undisputedly would count toward the PTO’s three-year allotment in a case not involving a continued examination. There is no basis for distinguishing a continued-examination case.

As already noted, the PTO has explained that § 154(b)(1)(B) is best understood as making distinctions based on whether certain delays are attributable to the PTO. On that basis the PTO has properly insisted that continued examinations are not to be distinguished according to when they are initiated. By the same token, allowance-to-issuance time is not to be distinguished according to whether there is a continued examination in a prosecution. Either way such time is plainly attributable to the PTO.

The language of “examination” used in § 154(b)(1)(B) reflects that underlying principle. An “examination” presumptively ends at allowance, when prosecution is closed and there is no further examination on the merits in the absence of a special reopening. The Notices of Allowance for the ’155, ’518, and ’631 patents here read: “THE APPLICATION . . . HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.” J.A. 291 (the ’155 patent); J.A. 367 (the ’518 patent); J.A. 488 (the ’631 patent). And the Manual of Patent Examining

Procedure, in §§ 1305, 1309, indicates that, when a notice of allowance is mailed, the application moves from the examiner to the office of publication. The common-sense understanding of “time consumed by continued examination,” 35 U.S.C. § 154(b)(1)(B)(i), is time up to allowance, but not later, unless examination on the merits resumes.

The PTO identifies several circumstances in which affirmative action is taken to resume examination after allowance, perhaps based on new information submitted by applicants in fulfillment of their continuing duty to disclose information material to patentability, 37 C.F.R. § 1.56. *See, e.g., BlackLight Power, Inc. v. Rogan*, 295 F.3d 1269, 1273-74 (Fed. Cir. 2002) (even after payment of the issue fee, but before issuance, PTO officials can take “extraordinary action to withdraw a patent from issue” and “return the . . . application to examination”); 37 C.F.R. § 1.313(a) (applicant may request resumption of examination). But such circumstances are exceptional, and an appropriate adjustment can be made when they occur. For none of the three applications at issue does the PTO identify any “continued examination of the application” that occurred after the notice of allowance was mailed. The possible existence of these exceptional cases does not support a general rule excluding time between allowance and issuance. In the present case, time after allowance was not time caused by the continued examination. Because the PTO applied the contrary view in calculating the patent term adjustment for the ’155, ’518, and ’631 patents, those calculations must be corrected.

CONCLUSION

For the foregoing reasons, we affirm the dismissal of Novartis’s claims with respect to fifteen patents as untimely, partly reverse the judgment as to patent term adjustment for the ’155, ’518, and ’631 patents, and remand for redetermination of the proper adjustments in accordance with this opinion.

No costs.

**AFFIRMED IN PART, REVERSED IN PART, AND
REMANDED**